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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/874,141	06/06/2001	Anderson Darrell	P 0280632 1995-30-0231CP2	6256
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909 7590 07/16/2003

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EXAMINER

GAMBEL, PHILLIP

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. <b>09/874141</b>	Applicant(s) <b>ANDERSON</b>	
	Examiner <b>GAMBEL</b>	Art Unit <b>1644</b>	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 4/3/03

2a) ☐ This action is FINAL.      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) \_\_\_\_\_ is/are pending in the application. 1-15

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 1, 6, 15

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) \_\_\_\_\_ is/are rejected. 2-5

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**BEST AVAILABLE COPY**

PAPER NO. 17

### DETAILED ACTION

1. Applicant's election with traverse of multiple sclerosis (Group II-C) as the disease species in Paper No. 15, filed 4/3/03, is acknowledged.

Applicant traverse on the ground that the disease species all require treatment with gp39 antibodies and that the effectiveness of each treatment can be similarly determined by assaying disruption of CD40/gp39 signaling.

As pointed out previously in the last Office Action (Paper No. 13), the disease species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

Applicant's previous election with traverse of Group II (claims 2-7) in Paper No. 12 was acknowledged. The traversal was on the ground(s) that Groups II / III /IV should be examiner together because all of these claims are directed to the use of anti-gp39 antibodies having a novel non-agonistic property. Inventions II/III/IV are different methods of use, which require different ingredients, process steps and endpoints. Therefore, they are patentably distinct. This was not found persuasive because of the reasons of record.

The requirement was still deemed proper and was therefore made FINAL

Claims 2-5 as they read on treating multiple sclerosis with anti-gp39 antibodies are under consideration as the elected invention.

For examination purposes, claim 3 is being included only to the extent that IL-2 secretion would be a by-product of the inflammatory response of multiple sclerosis or a property of anti-gp39 (anti-CD40 ligand) antibodies in the claimed methods. IL-2 secretion itself does not cause multiple sclerosis.

Claims 1 and 6-15 are withdrawn from consideration as they read on non-elected inventions and species.

2. The filing date of the instant claims is deemed to be the filing date of the provisional application 60/209,584, filed 6/6/00.

Applicant cannot claim priority USSN 08/554,950, filed 11/7/95, now U.S. Patent No. 6,001,358, which issued 12/14/99 because there was no copendency between the instant USSN 09/874,141 and USSN 08/554,950.

Applicant should amend the first line of the specification to delete the reference to the asserted priority document USSN 08/554,850.

4. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the <sup>TM</sup> or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

5. Claims 2-5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 2-5 are indefinite in the recitation of "modulating" because the claims fails to state the function which is to be achieved. The term "modulating" is relative in nature, which renders the claims indefinite. The term "modulating" is not defined by the claims; the specification does not provide a standard for ascertaining the direction, requisite degree or endpoint, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention

B) Claim 3 is indefinite in that IL-2 secretion may be a byproduct of the inflammatory response of multiple sclerosis (as well as the other diseases and conditions encompassed by the broad claims), but IL-2 secretion itself does not cause multiple sclerosis (or the other diseases and conditions encompassed by the broad claims).

Applicant should delete this claim or at least the recitation of "caused by IL-2 secretion".

If applicant intends to claim certain functional characteristics of anti-gp39 antibodies in the claimed methods, then applicant should claim such functions in a less ambiguous and confusing manner.

- C) Applicant should specifically point out the support for any amendments made to the disclosure.  
See MPEP 714.02 and 2163.06

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 2-5 are rejected under 35 U.S.C. § 102(a)(e) as being anticipated by Black et al. (U.S. Patent No. 6,001,358) (see entire document).

Black et al. Teach methods of treating disease condition wherein gp39 inhibition is therapeutically beneficial (columns 13-14 and 31-34), including multiple sclerosis with column 14, line 40 and column 32, line 67) with antibodies that bind gp39 (CD40 ligand), which block signals delivered via CD40 (See Examples 2, 3 columns 22-23; Examples 11-17 on columns 28-38 (see entire document).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat multiple sclerosis with anti-gp39 (anti-CD40 ligand antibodies). It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure

For examination purposes, claim 3 is being included only to the extent that IL-2 secretion would be a by-product of the inflammatory response of multiple sclerosis or a property of anti-gp39 (anti-CD40 ligand) antibodies in the claimed methods. IL-2 secretion itself does not cause multiple sclerosis.

8. Claims 2-5 are rejected under 35 U.S.C. § 102(e) as being anticipated by Noelle et al. (U.S. Patent No. 6,328,964) (see entire document).

Noelle et al. teach methods of treating T cell mediated disorders such as multiple sclerosis with anti-gp39 (anti-CD40 ligand) antibodies (See entire document; including Summary of the Invention on column 2; T Cell Mediated Autoimmune Diseases on column 3 and Claims 1-6)

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat multiple sclerosis with anti-gp39 (anti-CD40 ligand antibodies). It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure

For examination purposes, claim 3 is being included only to the extent that IL-2 secretion would be a by-product of the inflammatory response of multiple sclerosis or a property of anti-gp39 (anti-CD40 ligand) antibodies in the claimed methods. IL-2 secretion itself does not cause multiple sclerosis.

9. No claim allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
June 27, 2003